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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/840,485	04/23/2001	Rocky Barry Bigbie	AM100123	5730

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EXAMINER
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ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 03/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/840,485	BIGBIE ET AL.	
	Examiner	Art Unit	
	Khatol S Shahnan-Shah	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *3,9 and 15-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2,4-8 and 10-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicants' response to restriction requirement mailed 10/21/2002 paper # 12 is acknowledged. Applicants elected with traverse the invention of group I and species a) of group I. Claims 1- 2, 4-8 and 10-14 are readable thereon. Claims 3, 9 and 15-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions.

The traversal is on the ground(s) that searching for groups II and III will not put additional burden upon the office when searching for elected group I, has been noted. This is not found persuasive because the several inventions above are independent and distinct, each from the other for the reasons stated. They have acquired a separate status in the art as a separate subject for inventive effect and requires independent searches. The search of each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of one group would not necessarily anticipate or make obvious any of the other groups.

Applicants further argue that the restriction is in error in its classification of groups I, II and III. Applicants argue that the restriction requirement as stated is based on incorrect and artificial classification, is improper and should be withdrawn.

This is not found persuasive because Group I as classified under classes 424 subclasses 269.1 and 130.1 represent the correct classification. This application has been classified by USPTO under class 424, subclass 269.1, which represent an antigen or immunospecific vaccine from protozoan parasites. Subclass 130.1 represent antibodies including merozoites antibodies. As far as group II the invention is drawn to a

multicomponent composition comprising multiple or conjugate antibodies. In classifying group III, the examiner apologizes for a typographical error. The correct group is 435 subgroup 7.22.

The restriction requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-22 are pending.

3. Claims 1-2, 4-8 and 10-14 are under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-2, 4-8 and 10-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The invention appears to employ novel strains of parasites. It is not clear if the written description is sufficiently repeatable to avoid the need for a deposit. Further it is unclear if the starting materials were readily available to the public at the time of invention.

It appears that a deposit was made in this application as filed as noted on page 8 of the specification. However, it is not clear if the deposits meet all the criteria set forth in 37 CFR 1.801-1.809, and it is not clear that organisms having the accession number of ATCC PTA 2972 are known and publicly available or can be reproducibly isolated from nature without undue experimentation. Without a publicly available deposit of the above

strains, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of the strains is an unpredictable event.

Applicant's referral to the deposit of strains of ATCC PTA 2972 on page 8 of the specification is an insufficient assurance that all required deposits have been made and all the conditions of 37 CFR 1.801-1.809 have been met.

If the deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by the International Depository Authority under the provisions of the Budapest Treaty and that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application. These requirements are necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of the deposit and the complete name and full street address of the depository is required.

If the deposits have not been made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR 1.801-1.809, assurances regarding availability and permanency of deposits are required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a

statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

> (a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request;
>
> (b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;
>
> (c) the deposits will be maintained in the public repository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and
>
> (d) the deposits will be replaced if they should become nonviable or non-replicable.

In addition, a deposit of biological material that is capable of self-replication either directly or indirectly must be viable at the time of deposit and during the term of deposit. Viability may be tested by the repository. The test must conclude only that the deposited material is capable of reproduction. A viability statement for each deposit of biological material not made under the Budapest Treaty must be filed in the application and must contain:

> 1) The name and address of the depository;
> 2) The name and address of the depositor;
> 3) The date of deposit;
> 4) The identity of the deposit and the accession number given by the depository;
> 5) The date of the viability test;
> 6) The procedures used to obtain a sample if test is not done by the depository; and
> 7) A statement that the deposit is capable of reproduction.

As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the deposit was made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the strains described in the specification as filed is the same as that deposited in the depository. Corroboration may take the form of a showing a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

> Applicant's attention is directed to In re Lundack, 773 F.2d.1216, 227 USPQ (CAFC 1985) and 37 CFR 1.801-1.809 for further information concerning deposit practice.

5. Claims 5-8 and 10-14 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an immunogenically active component useful for production of antibody, does not reasonably provide enablement for a vaccine. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In the instant case claims 5-8 and 10-14 are drawn to a vaccine. The specification pages 13-23 describes vaccine preparation, adjuvant formulation, antibody response to intramascular injection of the vaccine, IFA serology and in vitro plaque reduction. However the specification fails to show whether or not the antibody was protective

against infection.

When a compound or composition claim is limited by a particular use, enablement of that claim should be evaluated base on that limitation. See in re Vaeck, 947 F. 2d 488, 495,20 USPQ 2d 1438, 1444 (Fed Cir, 1991). In the instant case the term vaccine means that infection was prevented. However specification pages 15-16 describes the generation of the antibody response measured by the IFA test. It is not clear how does this correlate to immunity? Otherwise the specification only enables the preparation of the antibody. It is not established if the antibody protects horses against the parasites. The specification does not provide substantive evidence that the claimed vaccine is capable of inducing protective immunity for prevention or amelioration of equine protozoal myeloencephalitis.

The prior art teaches that "Currently, there are no vaccine to protect equids from the parasites". See WO 01/15708 A1, page 2. (Applicants' 1449).

Given the lack of guidance on how to obtain the desired effect using a composition comprising an immunogenically active component in a method of preventing equine protozoal myeloencephalitis infection, and in light of the teachings of the prior art which teaches that currently, there are no vaccine to protect equids from parasites the skilled artisan could not make and use the claimed invention. And one skilled in the art will not be able to make/and or use the invention without undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claims 1-2, 4-8 and 10-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "capable" in claim 1 is a relative term, which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The term "optionally" in claim 5 is a relative term, which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

It is not clear what constitute the meets and bounds of the limitations of " about 1% to 50%" and " about 5% to 20%" in claims 10 and 11.

It is not clear what constitutes the meets and bounds of the limitation of " sufficient quantity" in claims 4 and 6.

It is not clear what constitutes the meets and bounds of the limitation of " amount sufficient" in claims 8 and 9.

It is not clear what applicants intend in recitation of " An effective immunizing amount" in claim 5.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the inventio was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Granstrom et al. (Journal Veterinary Diagnostic Investigation, Vol.5, pp. 88-90, 1993).

Claims are drawn to an immunogenically active component useful for preventing or ameliorating equine protozoal myeloencephalitis infection, which comprises inactivated Sarcocystis neurona. Note: The claims are viewed under elected invention species (a), which is drawn to inactivated Sarcocystis neurona merozoites.

Granstrom et al. teach antigens of cultured Sarcocystis neurona merozoites. They teach eight different immunogenically active components of Sarcocystis neurona (see abstract). Granstrom et al. do not teach that this composition is useful for preventing or ameliorating equine protozoal myeloencephalitis disease. However, intended use does not impart any critical impact or weight on the physical preparation and the patentability of the product.

Conclusion

8. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached on Monday through Friday from 7:30 AM - 4 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith, can be reached on (703) 308-3909. The fax

phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

Art Unit 1645

March 21, 2003

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